SERVICE MANUAL BodyFlowTM-P2CH/-P1CH

Revision: 11 / 2007





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Bodyflow™ is made in Germany in compliance with the quality requirements of ISO 9001 and the applicable safety standards and regulations of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

A conformity check acc. to Annex II, approved by the notified body 1275, was carried out.

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1 Technical Data

Protection class acc. to VDF 0750 / IEC

Table 1: Treatment

601	Battery Mode Only,	Type BF
Table 2: Charging		
Protection class acc. to VDE 0750 / IEC 601	II	
Input voltage	17 VDC	
Input current	0.8 ADC	
Power Supply	7.2 V 1350mAh	Ni-MH Accumulator

Table 3: General Technical Data

CE characterization	acc. to Council Directive concerning medical devices (93/42 EEC)
Class acc. to Council Directive concerning medical devices	IIa
Ambient temperature (operation)	+ 10 °C + 40 °C
Storage temperature	+ 10 °C + 40 °C
Dimensions (W x H x D)	17.5 cm x 4.5 cm x 10 cm
Weight	0.485 kg

Table 4: Battery Charger

Type (to be used exclusively)	Switchmode Charger FW 7219 / NI 4-10 NTC
Mains supply	100 240 VAC
Input current	0.1 0.3 A
Mains frequency	50 60 Hz
Output voltage	17 VDC
Output current	0.8 ADC

Table 5: Stimulation Current Output Parameters

	Standard	Light
Current	40 mA	40 mA
Resistance	500 Ohm	500 Ohm

Manufacturer Address

PHYSIOMED ELEKTROMEDIZIN AG

Hutweide 10

91220 Schnaittach/Laipersdorf

Germany

2 Instrument Overview





Table 6: Legend

1 Display	2 Function Keys
3 Intensity Control Circuit I	4 Intensity Control Circuit II (only BodyFlow [™] -P2CH)
5 Output Indicator	6 Power Connector
7 Power Switch	8 Patient Lead Connector

Table 7: Symbols



Type BF component, not connected to protective ground wire!

2.1 Setmenue

In the Setmenue, you can adjust the following device parameters:

Symbol	Meaning
0	Contrast of the Display <1>
☼	Brightness of the Display <1>
*	Back to start screen

2.2 Introduction

With your Bodyflow™ you have acquired a high-quality and extremely versatile unit for stimulation current therapy. The instrument will only show its true potential, however, if you are well informed about its functions. For this reason, carefully read the Operating Instructions and familiarize yourself with the use of the instrument.

2.3 General Notes

The instrument complies with the technical specifications of IEC 601, VDE 0750 and is assigned to class IIa according to the Council Directive concerning Medical Devices.

The instrument may only be operated by qualified personnel who have undergone special training. You must operate the instrument properly, i.e. in accordance with the Operating Instructions.

It is not intended for operation in explosion hazard zones or hydrotherapy rooms. Drastic temperature changes should be avoided, since condensation could be caused within the instrument. Do not start up the instrument until it is in temperature equilibrium with its environment!

Operating the instrument in the proximity (e.g. 1 m) of a short-wave or micro-wave therapy unit may cause output irregularities and should be avoided for this reason. Simultaneous connection of the patient to high-frequency surgical instrument should also be avoided.

Using the electrodes near the chest can increase the risk of heart beat irregularities.

2.4 Instrument Description

Bodyflow™ is a portable stimulation current therapy unit. The device is equipped with a rechargeable battery and is intended to be used as a mobile unit, e.g. in situations where no connection to the mains is available. This unit can only be used on battery power and not whilst plugged into mains power.

The function of Bodyflow[™] is controlled by a microprocessor. Essential components are permanently controlled by the processor and thus malfunctions are prevented. After switching on, all instrument functions are checked during an automatic self-test routine.

The instrument complies with all current safety standards. It meets the requirements of the EC directive concerning medical devices (93/42/EEC) and is therefore CE-labelled.

Bodyflow[™] has two modes of operation:

- Treatment: In this mode, the instrument is disconnected from the mains. When the battery charger is plugged in, the instrument cannot be switched on and treatment is not possible. Plugging in the battery charger into the instrument during treatment has the consequence that treatment is being interrupted and the intensity will be automatically turned down to zero and the instrument switches off.
- Charging: Charging is only possible when the device is switched off (refer to Mains and Battery Operation on page 16).

3 Calibration

The following service instructions allow you to do a basic calibration.

Usually for later balancing (e.g. repairs) the entire balancing procedure is performed. Only occasionally, if severe errors concerning the balancing procedure are not apparent or have been cleared, it may be limited to individual components.

This service manual covers one channel devices (BodyFlow TM -P1CH) as well as two channel devices (BodyFlow TM -P2CH).

When a second channel is indicated, the respective instructions are only valid for BodyFlowTM-P2CH, but not for BodyFlowTM-P1CH!

Parameters only valid for the second channel are written in italics.

3.1 Additional Equipment Required

	State of calibration*
Oscillograph with probe	В
Digital multimeter	В
Frequency meter	В

^{*}State of calibration B = precision 2 %

For information necessary for the calibrating procedure such as positions of the trimmers or test points, refer to the wiring scheme and the parts list from page 19.

4 Test Menu

To access the test menu, a jumper has to be set at the pins 1 + 2 of the socket X1 PM0615-1 before starting up the instrument. When switching on the instrument, you can access the test menu then.

Screen 1: Output Current



Selectable parameters for functional testing

0 – 60 min		
<u>CH1</u> 0 – 40mA	<u>СН2</u> 0-40mA	
Ti 1 – 10ms	Ri 0 – 950ms	
pole plus pole	auto pole minus	
-> Proceed to screen	2 (maximum intensity)	

Select the required parameter using the NAV buttons and press ENTER to confirm (e.g. the timer value will be highlighted and flash).

Use the NAV buttons to modify the parameter value. To check the output signals of CH1 (and CH2), use an oscillograph and a resistive load of 500 Ohm.

Screen 2: Checking the displayed value at maximum intensity without output load



CH1	Required value	Actual value	Output voltage		
	DCmA	DCmA	DCV		
CH2	Required value	Actual value	Output voltage		
	DCmA	DCmA	DCV		
	CH1 / CH2	2 digital value			
	Imax Test function	on "Trigger safety s	shutoff"		
	Pressing ENTER k	ey: Imax = 45 -5	5 DCmA		
< -	Return to screen 1	-> Proce	eed to screen 3		

Screen 3: Checking the displayed value at maximum dose with <u>resistive output load</u> CH1 500 Ohm / CH2 500 Ohm

Calibrating actual value vs. required value

40mA	40 m	A	190	
40mA	40 m	A	190	
CH1	110 C	H2	110	
(*)	Imax	51	mA	
+				

CH1	Required value	Actual value	Output voltage		
	DCmA	DCmA	DCV		
CH2	Required value	Actual value	Output voltage		
	DCmA	DCmA	DCV		

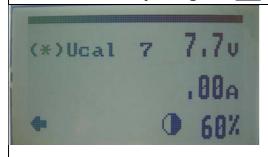
CH1 / CH2 digital value

Imax Test function "Trigger safety shutoff"

Pressing ENTER key: Imax = 45 -55 DCmA

< - Return to screen 2 -> Proceed to screen 4

Screen 4: Calibration of Ubatt (DCV) Attention! Battery charger is not connected



Enable the selection field **Ucal** (cursor flashes).

Measure **Ubatt** at the battery using the digital multimeter. Set the measured value in the display using the NAV buttons.

Charging current

<- Return to screen 2

Contrast of the Display <1>

Screen 5: Charging current Attention! Battery charger <u>is</u> connected



Enable the selection field **Ucal** (Cursor flashes).

Measure **Ubatt** at the battery using the digital multimeter. Set the measured value in the display using the NAV buttons.

Charging current

The measured value DCA is calculated by the microprozessor!

<- Return to screen 2

Contrast of the Display <1>

Finally:

- 1. Unplug the battery charger when charging is finished.
- 2. Remove the jumper at X1 (pins 1 and 2) and switch of the device!

5 Selftest

To execute the instrument selftest, press the following key sequence when in therapy mode: Pres **ENTER <2>** and **POWER <7>** simultaneously.

You have to press both keys until you have checked the following display values:

Screen 6: Instrument Selftest



CH1	Optocoupler	Value	Value						
'	check		40mA +/- 10%						
	value ≤ 5	10%							
CH2	CH2 Optocoupler								
(only for	check	25mA +/-							
P2CH)	value ≤ 5	10%							
Imax Test fu	Imax Test function "Trigger safety shutoff"								

Imax Test function "Trigger safety shutoff"
Pressing ENTER key: Imax = 45 -55 DCmA

When the instrument selftest has detected no problems, the following message is displayed:

"NF . . OK " + "Imax . . OK "

In the case of a problem, a monitoring note is displayed instead of OK (refer to page 18)!

6 Controls and Indicators

The design of Bodyflow[™] allows for easy operation. Because of its small size, the instrument is very easy to transport. It has been designed for operation both inside and outside of therapy rooms, and is fed by rechargeable batteries for that reason (refer to Mains and Battery Operation on page 16).

All controls and indicators are integrated into the housing, thus allowing for easy cleaning of the instrument's surface and protecting it from dust.

The instrument's microprocessor monitors the safety-related components, prevents from malfunctions and checks the instrument after switching it on.

6.1 Display <1>



The **Display <1>** shows all menu items including the therapy parameters of the instrument. You can select the parameters using the **Function Keys <2>**.

Symbols in the Upper Status Bar

The upper status bar shows the following symbols:

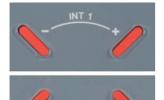
	Button to open the popup menu
Standard	Currently selected menu
<u></u>	State of charge of the battery (refer to <u>Mains</u> and <u>Battery Operation</u> on page 16)

6.2 Function Keys <2>



The **function keys <2>** are used to select the therapy parameters and to operate the instrument. After switching on the instrument, the **Display <1>** shows the start screen. You can now access the desired therapy program by pressing the right or left key. To select an item, simply press the **ENTER** button in the middle.

6.3 Intensity Control Circuit I <3> and Circuit II <4>



Intensity Control Circuit I <3> and Intensity Control Circuit II <4> (only BodyFlowTM-P2CH) serve to set the intensity in the circuits I and II in steps of 0.5 mA. When turning up the intensity of the two intensity controls, the associated therapy timer in the **Display <1>** will be started as well.

Automatic Output Current Switch-off

Bodyflow[™] features an automatic output current switch-off, activated in case the current flow of the electrodes is interrupted (electrode falls off or is disconnected from the instrument). The symbol ^{***} will appear in alternation with the intensity on the **Display** <1> and the current will be automatically turned down to a minimum basic current in the respective circuit. The timer stops the therapy time.

To eliminate the error, you have to press the button with the minus symbol of **Intensity Control Circuit I <3>** or **Intensity Control Circuit II <4>** one time to be able to continue. The message will disappear and you can increase the intensity again.

6.4 Output Indicator <5>

The **Output Indicator <5>** tells you to be cautious when handling the electrodes.

Caution



When the **Output Indicator <5>** flashes, the **Patient Lead Connector <8>** is under voltage!

Make sure you do not touch the electrodes when the current is turned up! Touching the electrodes with your fingers may startle as the electrodes need to disperse the current evenly!

6.5 Power Connector <6>



The **Power Connector <6>** is located at the front side of the instrument. Here, you plug in the supplied battery charger if you want to charge the batteries.

6.6 Power Switch <7>



The **Power Switch <7>** is on the bottom of the instrument's upper side. By means of this switch, you can switch the instrument on and off. After switching on, a selftest is automatically carried out by the instrument.

6.7 Patient Lead Connector <9>

The **Patient Lead Connector <8>** on the front side of the instrument serves to plug in the electrodes.



● ● ● ● The two connectors on the left (seen with the instrument facing up) are assigned to circuit I, the two on the right to circuit II.

The polarity is of no importance, since the instrument operates in biphase mode.

7 Operation of the Device

The operating steps not directly relating to the therapy are described in the following paragraphs.

7.1 Mains and Battery Operation

At battery operation, the battery has to be fully charged before operating it for the first time. The typical life expectancy of this battery and it's recharge life is 500 cycles or recharges.

The charging status of the batteries is displayed on the **Display <1>**:

Battery Charge	Symbol
0%	- :
25%	
50%	
75%);
100%	<u> </u>

How to Charge the Battery

If you want to charge the battery, proceed as follows:

- 1. Plug the supplied battery charger into the **Power Connector <6>** on the front side of the device.
- 2. The batteries are being charged. When the batteries are completely discharged, the charging procedure will take approx. 3 hours.

Important

In order to ensure a long battery life, the batteries must be charged completely when first charged. The first charging procedure should not be interrupted!

7.2 Notes on Handling the Batteries

If the battery capacity is very low during operation, the 3-step warning system is activated:

- a. The charging status symbol flashes.
- b. An acoustic signal sounds every second and the charging status symbol flashes. The intensity is reduced prematurely.
- c. The device shuts down to avoid complete discharging of the batteries.

In this case, recharge the battery, as described in section <u>How to Charge the Battery</u> on page 16.

Important

If the unit is not used for a longer period of time, please fully charge the battery once a month. This will help to avoid exhaustive discharge.

7.3 Battery Charger

The supplied battery charger (Ref. No 00584) has an LED to indicate the current state of the batteries.



Battery Charger

Depending on the current state of the batteries, the LED is illuminated or flashing in green or yellow. This has the following significance:

State of Battery Charger	LED Light Code
Standby	LED is permanently yellow
Precharge	LED flashes slowly in yellow
Rapid Charge	LED flashes quickly in green
Maintain	LED flashes slowly in green
Error	LED flashes quickly in yellow
Ready	LED is permanently green
Wait	LED flashes slowly in green and yellow (alternating)

The battery charger can be equipped with different primary adaptors to match the line voltage of the destination country. One primary adaptor for the respective country is in the scope of delivery.

7.4 Economy Mode

The unit automatically switches over to the economy mode to save power. This will occur after approx. 20 seconds. The **Display <1>** is no longer illuminated. Pressing any key will re-activate the illumination.

8 Monitoring Notes

8.1 Selftest

ERROR CODE	Monitoring note
MUXERR	101
DACERR	102
NFERR	105
ImaxERR	106
NFERR CH2	125

8.2 Therapy

ERROR CODE	Monitoring note
I20% ERROR CH1 / CH2	201
Imax H_ERROR CH1 / CH2	202
Imax S_ERROR CH1 / CH2	203
T/R ERROR CH1 / CH2	204
0mA/0V ERROR CH1 / CH2	205
Imax S_INT_ERROR CH1 / CH2	206

8.3 Battery Charger

Test	Monitoring note
Battery charger connected, TEST OKAY	***
Battery charger connected, TEMPERATURE SENSOR FAULT	901
Battery charger connected, CHARGING CURRENT MEASUREMENT FAULT	902

9 Appendix

Date: 28.11.2007 12

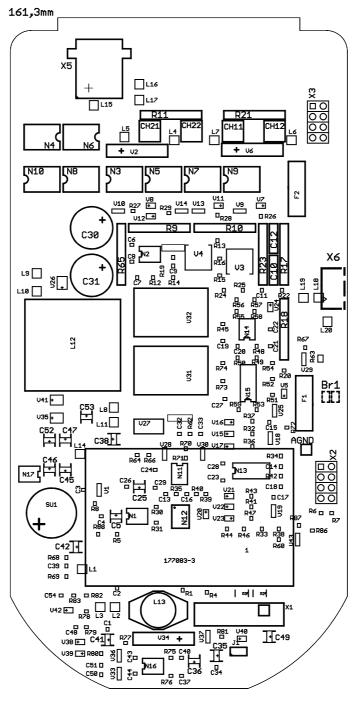
part number / O-No description / ND step/cost perpos.no. item notice quantity

p.ID: 01151 var./sw: 1/0-0-0 desc 1/2:Bodyflow portable mit Zubehör Zweikanalversion

O#: 01151 **desc 3/4:**Drainagegerät

ND: BODYFLOW desc 5/6: Ersteller1egl desc 7/8:

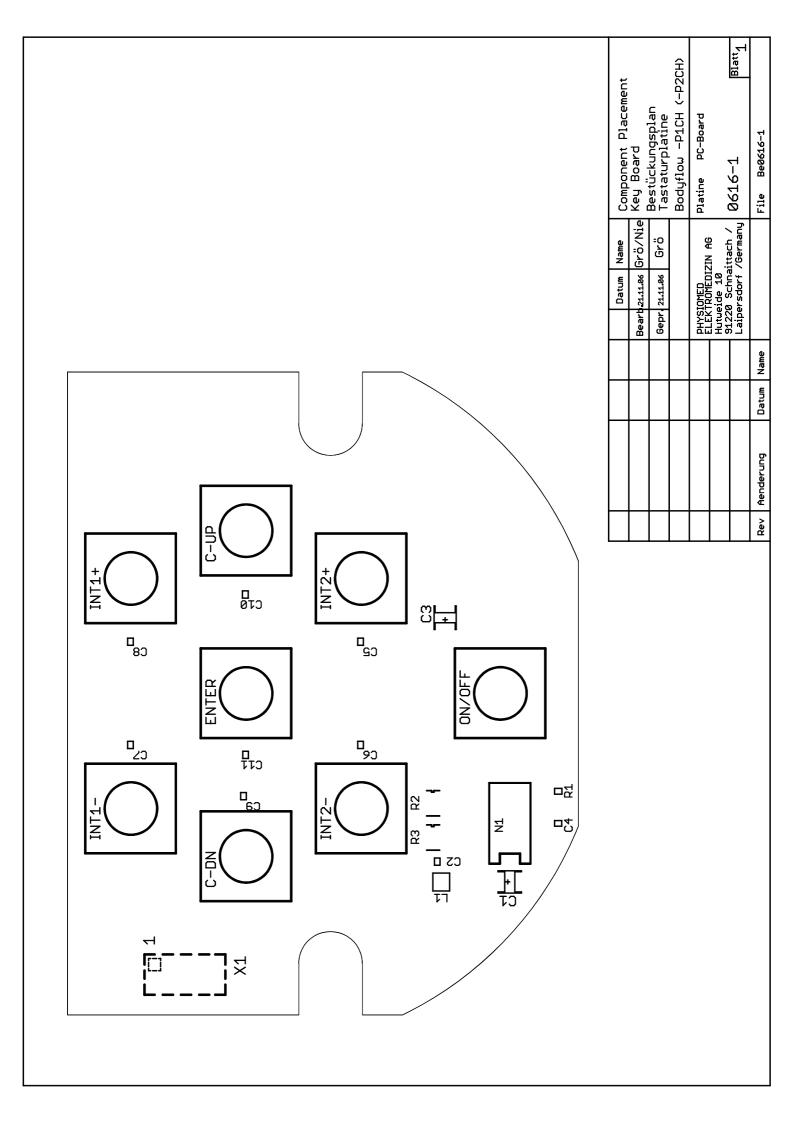
E4606	[41]		4	4	4	4.0000	Ctal
51696	[¶] housing lower pa bodyflow BF-P	rt	1	1	1	1,0000	Stck
51695	[¶] housing upper particles bodyflow BF-P	art	1	1	2	1,0000	Stck
51697	[¶] vision panel 1 ch bodyflow BF-P	annel	1	100	3	1,0000	Stck
51720	[¶] vision panel 2 ch bodyflow BF-P	annel	1	100	4	1,0000	Stck
51698	[¶] keyboard pad 1- bodyflow BF-P	channel	1	100	5	1,0000	Stck
51721	[¶] keyboard pad 2- bodyflow BF-P	channel	1	100	6	1,0000	Stck
51723	[¶] 0615-1/2-CH ma bodyflow BF-P	inboard	1	1	7	1,0000	Stck
51726	[¶] 0503-1/PVB produced bodyflow BF-P	essor board	1	1	8	1,0000	Stck
51724	[»] 0616-1 keypad b bodyflow BF-P	oard	1	1	9	1,0000	Stck
51725	[»] 0617-1 display b bodyflow BF-P	oard	1	1	10	1,0000	Stck
51734	[¶] accumulator FT 7,2-02		1	1	11	1,0000	Stck
51735	[¶] insulating plate/ bodyflow BF-P	Accu	1	1	12	1,0000	Stck
51699	[¶] rubber foot bodyflow BF-P		1	1	13	4,0000	Stck
51739	[¶] TEXAS socket 3- bodyflow BF-P	pole	1	1	14	1,0000	Stk
51700	[¶] plug socket hold bodyflow BF-P	er	1	100	15	1,0000	Stck
51740	[¶] plug socket 2mm bodyflow BF-P	(red) MLA2-G	1	100	16	2,0000	Stck
51741	[¶] plug socket (blace bodyflow BF-P	k) MLA2-G	1	100	17	2,0000	Stck

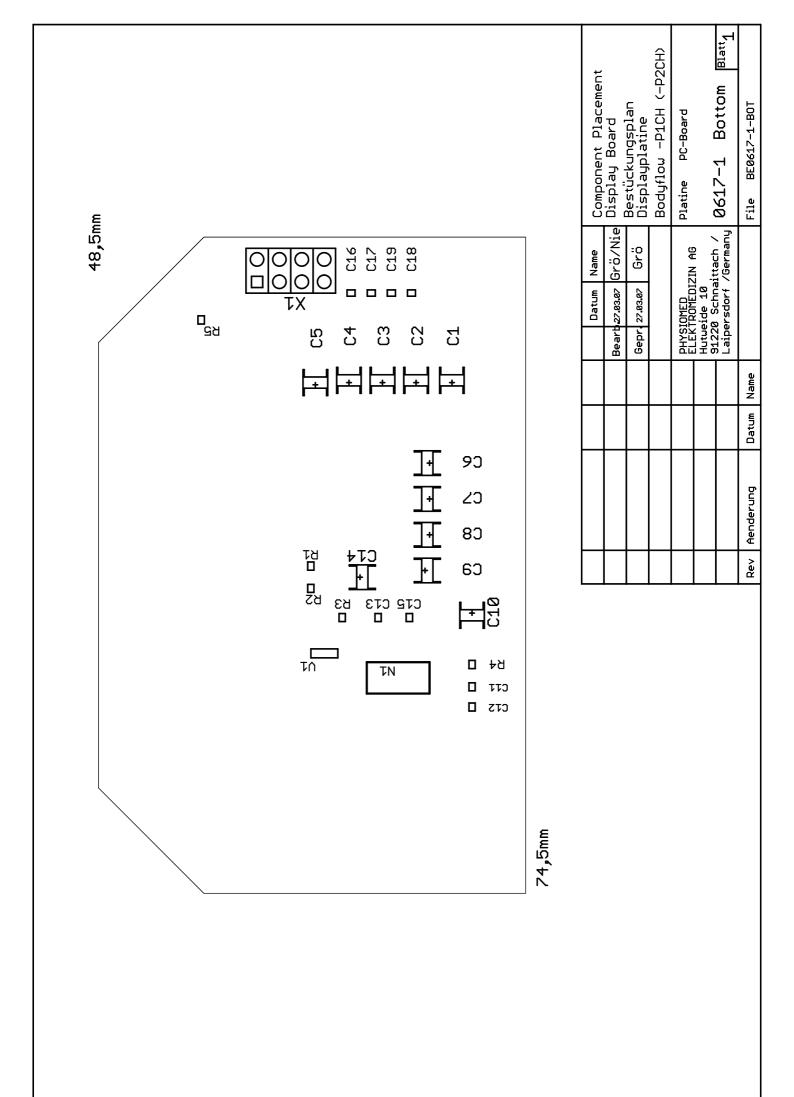


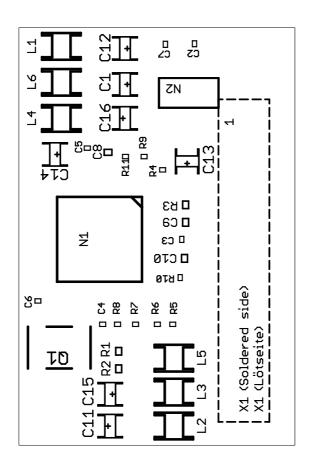
Soldered side: Lötseite: X2, X3, X6, Br1

79,5mm

				Datum Name Bearb. 15.06.07 Grö/Nie Gepr. 15.06.07 Grö		Component Placement Main Board			
						Bestückungsplan Hauptplatine			
							Bodyflow -P1CH (-P2CH)		
				PHYSIOMED ELEKTROMEDIZIN AG Hutweide 10 91220 Schnaittach / Laipersdorf /Germany			Platine	PC-Board	
							0615-1 Blad		Blatt
									1
Rev	Aenderung	Datum	Name				File	BE0615-1	







						$^{Blatt} 1$		
Component Placement	Processor Board	Bestuckungsplan Prozessorplatine	PHYSIOVAC – Basic	Platine PC-Board		Laipersdorf /Germany 0503-1_PUB	File Be0503-1_PUB	
Name	Bearb, 28.86.87 Grö/Au	Grö		ZIN AG) 41- NII	aipersdorf /Germany		
Datum Name	28.86.87	Gepr 28.86.87 Grü						
	Beart	Gepr		PHYSIOMED ELEKTROMEDIZIN AG Hutweide 10 91220 Schnaittach Laipersdorf /Germa				
							Name	
							Datum Name	
							Rev Aenderung	
							Rev	